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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN D. PACETTI, WOUTER E. ROORDA, and NI DING

Appeal 2008-3283
Application 10/040,538
Technology Center 1700

Decided: September 4, 2008

Before TONI R. SCHEINER, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-60, and 71-78. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-60, and 71-78 are appealed (Final Rejection 1). Claims 7, 12, 14, 37-40, 42, 43, 47, and 61-70 are listed in the appendix to the Appeal Brief, but these claims have been withdrawn from consideration (*id.*)

Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-60, and 71-78 stand rejected as follows:

1) Claims 1-6, 11, 13, 17-19, 21-24, 33-36, 44, 46, 48-54, 57-60, 71, and 72 under 35 U.S.C. § 102(e) as anticipated by Castro (US 6,395,326 B1, issued May 28, 2002) (Ans. 4);

2) Claims 9, 10, 15, 16, 20, 25, 26, 41, 45, 55, 56, and 73-78 stand rejected under 35 U.S.C. § 103(a) as obvious over Castro (Ans. 6).

3) Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60, and 71-78 under 35 U.S.C. § 103(a) as obvious over Ding (US 6,358,556 B1, issued Mar. 19, 2002) and You (US 6,407,009 B1, issued Jun. 18, 2002) (Ans. 8).

Claims 1, 23, 54, and 73 are the independent claims and read as follows:

1. A method of coating an implantable medical device comprising:
applying a composition, from a coating dispenser, including a solvent to an implantable medical device; and
directing a gas, from a gas dispenser positioned at a distance from the coating dispenser, onto the implantable medical device,
wherein if the solvent has a vapor pressure greater than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to decrease the evaporation rate of the solvent, and if the solvent has a vapor pressure of less than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to increase the evaporation rate of the solvent.

23. A method of coating an implantable medical device comprising:

applying a composition, from a coating dispenser, including a solvent to an implantable medical device; and

blowing a gas, from a gas blower positioned at a distance from the coating dispenser, directly onto the implantable medical device to either increase or decrease the evaporation rate of the solvent from the composition on the implantable medical device,

wherein if the solvent is non-volatile the temperature of the gas is adjusted to increase the evaporation of the solvent, and if the solvent is volatile the temperature of the gas is adjusted to decrease the evaporation rate of the solvent.

54. A method of coating a stent comprising;

positioning a stent on a support assembly;

applying a coating substance including a solvent from a dispenser to the stent;

blowing a gas from a blower onto the stent to either increase or decrease the evaporation rate of the solvent from the coating substance on the stent based on the volatile properties of the solvent; and

rotating the stent supported by the support assembly about a longitudinal axis of the stent.

73. A method of coating a stent comprising:

applying a composition, from a coating dispenser, including a solvent to a stent; and

blowing an inert gas, from an inert gas blower positioned at a distance from the coating dispenser, directly onto the stent to increase the rate of evaporation of the solvent from the composition on the stent.

ANTICIPATION BY CASTRO

Claims 1-6, 11, 13, 17-19, 21-24, 33-36, 44, 46, 48-54, 57-60, 71, and 72 stand rejected under 35 U.S.C. § 102(e) as anticipated by Castro.

Claim 1

Findings of Fact

1. Claim 1 is directed to a method of coating an implantable medical device.
2. The claim has two steps:

3. 1) applying a composition, including a solvent, from a coating dispenser; and

4. 2) "directing a gas, from a gas dispenser" which is positioned at distance from the coating dispenser.

5. The term "directing" is not defined in the Specification. We adopt its ordinary meaning: "to regulate the course of" or "to aim",[1] i.e., the gas dispenser aims or regulates the course of a gas toward a desired location.

6. The claim states that

> if the solvent has a vapor pressure greater than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to decrease the evaporation rate of the solvent, and if the solvent has a vapor pressure of less than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to increase the evaporation rate of the solvent.

7. Thus, a solvent vapor pressure of 17.54 Torr is a pivot point for determining how to adjust the temperature of the gas.

8. The claim does not require recognition of the 17.54 Torr pivot point.

9. The claim also does not require a structure for deciding at what solvent vapor pressure to adjust the gas temperature.

10. Consequently, we interpret the claim limitation to be met when: 1) the temperature of a gas is adjusted to decrease the evaporation of a solvent having a vapor pressure of greater than 17.54 Torr; or 2) the temperature of a gas is adjusted to increase the evaporation of a solvent having a vapor pressure of less than 17.54 Torr.

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[1] Direct: "to regulate the course of"; "to aim or send toward a place or object". THE RANDOM HOUSE DICTIONARY 375 (Rev. Ed. 1982).

THE CASTRO PATENT

11. Castro describes a dispenser assembly for controlled delivery of a composition on a prosthesis, such as a stent (Castro, at col. 8, ll. 53-67 and Abstract; Ans. 4).

12. Castro also describes "a heating assembly 52 . . . used for controlled drying and/or curing of a coating on prosthesis 12. As shown in FIG. 5A, heating assembly 52 can be a device including a heat conduit 54, a heating nozzle 56 having an orifice 58 through which heat is delivered" (Castro, at col. 11, ll. 11-15; *see* Ans. 4). There is no statement or indication in Castro that the coating or heating is performed in a vacuum; thus air would be present.

13. The diameter of the heating nozzle orifice can be varied (Castro, at col. 11, ll. 34-35). "For example, a larger orifice 58 may be utilized for application of heat to the entire outer surface of prosthesis 12 than the orifice 58 for the application of heat over discrete channels or cavities within prosthesis 12" (*id.*, at col. 11, ll. 38-41).

14. "In embodiments in which composition 10 includes a solvent, . . . the solvent may be removed from composition 10 on prosthesis 12 by allowing the solvent to evaporate" by heating (Castro, at col. 18, ll. 3-6; *see* Ans. 4).

15. Dimethlyacetamide is described by Castro as a useful solvent (Castro, at col. 13, ll. 9); it has a vapor pressure less than 17.54 Torr (Ans. 4).

CASTRO APPLIED TO CLAIM 1

16. Castro teaches applying a composition to a stent using a dispenser assembly (FF11). This disclosure meets the limitation recited in claim 1, step 1) of "applying a composition, from a coating dispenser" (FF1-2).

17. A heating nozzle 56 is used in Castro to apply heat to the composition to dry it, cure it and allow a solvent in the composition to evaporate (FF12, 14).
18. The nozzle can be directed at specific portions of the stent ("for the application of heat over discrete channels or cavities within prosthesis 12") (FF12-13).
19. The heat emanating from the heating nozzle orifice heats the air, and by convection, the heated air is carried to the specific portions of the prosthesis (*see* FF18). Thus, the heating nozzle regulates the course of and aims the heated air at the desired location on the prosthesis, meeting the limitation of "directing a gas" as recited in claim 1 (FF4-5).
20. When dimethlyacetamide is used as solvent in Castro's method (FF15), the heating nozzle would be used to evaporate it (FF14). Since dimethlyacetamide has a vapor press of less than 17.54 Torr (FF15), this step would meet the limitation of claim 1 of adjusting the temperature of a gas to increase the evaporation of a solvent having a vapor pressure of less than 17.54 Torr (FF10; Ans. 4).
21. In sum, Castro's method meets all the limitations of claim 1.

Analysis

Anticipation requires that a prior art reference describes all elements of the claimed invention. In this case, there is adequate evidence that Castro teaches all limitations of claim 1 (*see* FF16-21). Consequently, we turn to Appellants' rebuttal arguments and evidence.

Appellants argue that "Castro . . . fails to teach that the heating assembly does or is capable of directing a gas as claimed" (App. Br. 5). They contend:

> Application of heat in Castro can be by many means, such as a heated coil or a conductive pin positioned in the opening of the nozzle (charged pin that can glow and generate heat). Using gas cannot be read into the teaching of Castro since Castro has no indication of its use.

(*id.*)

This argument does not persuade us that the Examiner erred. Castro explicitly refers to a "heating nozzle" and its use to direct heat to specific locations on a coated stent in order to induce drying, curing, and evaporation (FF12-14). There is no statement or indication in Castro that the coating or heating is performed in a vacuum; thus air would be present (FF12). It is reasonable to believe that the heat produced by the nozzle heats *air* which would move by convection to the targeted discrete location on the prosthesis (FF19). As the Examiner put it: "It is immediately envisaged that it would take the motion of a fluid [the heated air gas molecules] to get from the remote heat source to the heating nozzle 56" (Ans. 12). Whether the heating element is a heated coil or conductive pin (*see* App. Br. 5), we agree with the Examiner that heating would reasonably be believed to produce a fluid motion of the air molecules aimed toward an object – thus meeting the "directing" limitation of claim 1.

Appellants argue that "the use of heated gas" might be a possibility or probability, but it is not necessarily present – the standard for anticipation (App. Br. 7).

However, there is a logical basis for believing that Castro teaches directing a heated gas (*see* Ans. 12; FF19) as in claim 1. The PTO does not have the ability "to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). Thus, once "the PTO shows sound basis for believing that the products of the applicant and

the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). In this case, the Examiner has a sound basis for believing that Castro's heat nozzle would direct a gas as required by claim 1. Appellants have not provided sufficient evidence to show that the Examiner erred in his reasoning.

Appellants provide declarations by listed inventors of the Castro patent, including Mr. Daniel Castro, Dr. Syed Hossainy, and Dr. Li Chen, each of whom states that the Castro patent does not teach the subject matter of claim 1. *See. e.g.,* paragraph Nos. 22, 18, and 8, respectively, of each declaration.

These declarations do not convince us that the Examiner erred. Each of the declarants state that the subject matter of claim 1 is not taught by the Castro patent, but no evidence or reason is provided for this conclusion. The Examiner has made clear factual findings about Castro's teaching and how they apply to the claimed invention (Ans. 4-5; *see* FF11-15). However, none of these facts are addressed in the declarations nor do the declarants identify any of the Examiner's allegedly "conjured and fallacious versions of Castro's teachings" (App. Br. 7). In sum, when the totality of evidence is considered, the declarants' opinions, which are unsupported by any factual findings or reasoning, do not outweigh the Examiner's evidence that the claimed invention is described by Castro.

Appellants also state that "Castro teaches absolutely no condition of temperature adjustment based on the vapor pressure 17.54 Torr" (App. Br. 5; underlining removed). They argue that the "mere" teaching of a solvent with a vapor pressure of less than 17.54, "does not amount to teaching a

method of adjusting gas temperature based on the volatility of the solvent used (*id.* at 5-6; underlining removed).

We have not interpreted claim 1 to require recognition of the 17.54 Torr decision point (FF8). Nor does the claim require a structure for deciding at what solvent vapor pressure to adjust the gas temperature (FF9). Rather, the claim limitation is met when the gas is heated to increase the evaporation of the solvent having a vapor pressure of less than 17.54 Torr (FF10). In this case, the solvent's vapor pressure is less than 17.54 Torr ("if the solvent has a vapor pressure of less than 17.54 Torr at ambient temperature") and the gas is heated to induce evaporation of the solvent (FF14, 20) ("the temperature of the gas is adjusted to increase the evaporation rate of the solvent") – thus the limitations of the claim are met.

For the foregoing reasons, we affirm the rejection of independent claim 1. Claims 2, 4, 5, 6, 11, 13, 17, 18, 21, 22, 34, 35, 36, and 71 fall with claim 1 because separate reasons for their patentability were not provided.

Claims 3 and 33

The Examiner contends that Castro teaches (at columns 11-12 and 18-19) "simultaneous" application of the composition with the directing of the gas as recited in claims 3 and 33 (Ans. 5). However, we agree with Appellants that this disclosure states that the heating assembly may follow the coating pattern on the prosthesis, but does not describe applying the composition at the same time as directing the gas (Reply Br. 7-8). Thus, we reverse the rejection of these claims.

Claim 19

Appellants argue that Castro does not disclose the limitations pointed out in claim 19 (App. Br. 9), but they do not identify any error in the Examiner's findings nor conclusion with respect to this claim (*see* Ans. 5). Consequently, we affirm the rejection for the reasons set forth by the Examiner.

Claims 23 and 54

Findings of Fact

22. Independent claims 23 and 54 recite "blowing" a gas from a "blower."

23. We interpret "blowing" from a "blower"[2] to mean that a gas is supplied by a machine ("blower").

24. Castro does not describe a utilizing a blower to blow a gas through the gas nozzle 58.

Analysis

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). Castro does not describe blowing a gas using a blower as recited in independent claims 23 and 54 (FF22-24). Consequently, we reverse the rejection of claims 23, 54, and dependent claims 24, 44, 46, 48-53, 57-60, and 72 as anticipated by Castro.

[2] Blower: "a machine for supplying air at a moderate pressure." THE RANDOM HOUSE DICTIONARY 146 (Rev. Ed. 1982).

OBVIOUSNESS OVER CASTRO

Claims 9, 10, 15, 16, 20, 25, 26, 41, 45, 55, 56, and 73-78 stand rejected under 35 U.S.C. § 103(a) as obvious over Castro.

Claims 9, 10, and 16

With respect to claims 9 and 10, the Examiner finds "that the nozzle 26 is positioned over or in contact with strut 68 of the stent ([Castro, at] col. 16, lines 50-51), and that the dispenser may be an ink-jet head, which is a type of spraying device (col. 8, line 59)" (Ans. 6). The Examiner states that the specific distance recited in claim 9 is not described in Castro, but that distance is a "result-effective variable" whose "determination . . . is within the skill of one practicing the art" (*id.* at 7).

Appellants state:

> An ink-jet head propels precisely measured volumes, i.e., micro-droplets, of a coating composition in a tightly defined stream. In contrast, spraying is used to maximize the effect of a liquid by increasing the total surface area of the liquid for better dispersion over a substrate. These two methods are quite different, and since no where does Castro teach or suggest the "spraying" of a coating composition, this new rejection is without merit.

(Reply Br. 7.)

While it may be true that "an ink-jet" would not spray a coating composition, we do not agree that "no where does Castro teach or suggest" spraying a coating composition (*id.*). According to Castro, "spray-coating methods" were known in the prior art (*see* Castro, at col. 2, ll. 7-9). Thus, we affirm the rejection of claim 9. Claims 10 and 16 were not separately argued and thus fall with claim 9.

Claim 15

The Examiner contends that the it would have been obvious to have utilized a gas flow rate of "about 300 feet/minute to about 10,000 feet/minute" as recited in claim 15 as flow rate is a results-effective variable (Ans. 6-7).

We agree with Appellants that Castro does not describe an active gas flow and thus there is no reason that persons of ordinary skill in the art would have selected the claimed values. We reverse the rejection of claim 15.

Claim 20

The Examiner states that inert nitrogen is a component of air and thus would be directed as in claim 20. Appellants contend that Castro "neither teaches nor suggests the use of nitrogen (Reply Br. 9).

The Examiner has the better argument. It is well-known that air is comprised of nitrogen. Appellants have not challenged this finding. Consequently, we affirm the rejection of claim 20.

Claim 41

Claim 41 is directed to the method of claim 1, "wherein the implantable medical device is a stent and wherein the stent is rotated during the coating process at a speed of 0.1 rpm or higher." The Examiner states rotation speed is a results-effective variable "depending upon the particular coating solution used, the size and shape of the stent being coated, the desired thickness, etc" whose optimal value could be determined by persons of ordinary skill in the art (Ans. 7).

Appellants argue that the rotational speed of the stent was not recognized as a results-effective variable (Reply Br. 8-9). This argument is not persuasive. Castro clearly teaches that the stent maybe rotated, i.e., by the holder assembly which holds the stent (Castro, at col. 4, ll. 57-62). Castro does not provide specific details about the rotational pathway, indicating that such determination – as the Examiner found – was reasonably understood to be within the skill of one practicing the art. Consequently, we affirm the rejection of claim 41.

Claims 25, 26, 45, 55, 56, and 73-78

Each of claims 25, 26, 45, 56, and 73-78 contains the limitation that the method comprises "blowing" a gas from a "blower." For the reasons stated above (FF22-24), we agree with Appellants that Castro does not describe blowing a gas using a blower. Consequently, we reverse the rejection of these claims.

OBVIOUSNESS OVER DING AND YOU

Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-58, 60, and 71-78 stand rejected under 35 U.S.C. § 103(a) as obvious over Ding and You.

THE DING PATENT

25. Ding teaches applying a coating to a stent by spraying (Ding, at col. 3, ll. 51-55; Ans. 8.)

26. "Ding et al. uses an evaporative solvent such as THF with a relatively high vapor pressure (col. 6, line 55 - col. 7, line 35). The vapor pressure of

THF is greater than 17.54 Torr at ambient temperature (129 Torr at 20 C)" (Ans. 8).

27. "The coating is exposed to room temperature ventilation for solvent evaporation (col. 3, lines 59-61)" (Ans. 8).

THE YOU PATENT

28. You describes a chamber for applying a film (You, Abstract).

29. You teaches a nozzle positioned over a wafer to dispense compositions (You, at col. 3, ll. 20-25; Ans. 15).

30. The chamber described in You has a "bias gas inflow source 124, which typically uses an inert gas such as . . . argon" (You, at col. 5, ll. 37-39).

31. The chamber also has a pump 120 which can be used to pump out gas, lowering the pressure of the chamber (You, at col. 5, ll. 32-34; at col. 6, ll. 3-13).

32. The temperature inside the chamber can be increased by heaters or decreased by coolers (You, at col. 5, ll. 48-50).

33. The temperature of the chamber can be regulated to control evaporation of solvent (You, at col. 5, l. 60 to col. 6, l. 6; at col. 7, l. 52 to col. 8, l. 10; at cols. 18-19; *see* Ans. 10).

Analysis

Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-53, and 71-78

Appellants contend that You does not teach directing a gas as in claim 1 or a gas blower for blowing gas as in claims 23 and 73 onto an implantable medical device (App. Br. 10). "Releasing a gas into a chamber to cool the chamber holding a semiconductor substrate is not equivalent to blowing a gas directly onto an implantable device" (*id.* at 11).

Claims 1, 23, and 73 each have the limitation that a gas is directed or applied directly "onto" a medical device. We have interpreted "directing" to mean that the gas is aimed towards the medical device (FF5). You describes a gas flow inlet (FF30) and a pump to take gas out of the chamber (FF31), but the Examiner has not presented evidence that this configuration would aim the gas onto the medical device. The Examiner has the burden of establishing prima facie obviousness of the claimed subject matter. In this case, there is no evidence that the gas would be aimed at the medical device as required by claims 1, 23, and 73. Thus, we agree with Appellants that the Examiner has not met the burden of establishing prima facie obviousness of claims 1, 23, and 73. Consequently, we reverse the rejections of claim 1, 23, and 73 and dependent claims 2-6, 9-11, 13, 15-22, 24-26, 33-36, 41, 44-46, 48, 49, 51-53, and 71, 72, and 74-78.

Claims 54-58 and 60

Appellants contend there "is absolutely no motivation in the references" to combine Ding with You in view of the different issues between stent coating as in Ding and semiconductor materials as in You (App. Br. 11-12). Appellants also argue that the references are not in the same field of invention or reasonably pertinent to the particular problem with which the claimed invention is concerned (App. Br. 12-14).

This argument is not persuasive. You, as Ding, is concerned with conditions for coating its devices. While the materials and purposes may differ, we are not convinced that persons of ordinary skill in the art would not have looked to You for guidance. In particular, Ding teaches the relevance of temperature for coating (Ding, at col. 8, ll. 27-42), coating a

device in a chamber equipped with a pump (*id.* at col. 8, ll. 59-63), the use of argon (*id.* at col. 8, 54), and solvent evaporation (*id.* at col. 3, ll. 59-61; FF26,27), the same coating parameters described in You (FF30-33). Thus, we agree with the Examiner's logic that persons of ordinary skill in the art would have combined You with Ding to have achieved the claimed invention.

Appellants arguments on pages 16-17 of the Appeal Brief appear to relate to the direct blowing limitation recited in claims 1, 23, and 73, which we agree is not suggested by the Ding/You combination. However, claim 54 does not require aiming a gas onto the medical device and is thus not distinguished by Appellants' argument regarding directed versus more 'controlled' drying (App. Br. 16).

For the foregoing reasons, we affirm the rejection of claim 54 as obvious over Ding and You. Claims 55-58 and 60 fall with claim 54 because separate reasons for their patentability were not provided.

CONCLUSION

1) The rejection of claims 1, 2, 4, 5, 6, 11, 13, 17-19, 21, 22, 34, 35, 36, and 71 as anticipated by Castro is affirmed.

2) The rejection of claims 3, 23, 24, 33, 44, 46, 48-53, 57-60, and 72 as anticipated by Castro is reversed.

3) The rejection of claims 9, 10, 16, 20, and 41 as obvious over Castro is affirmed.

4) The rejection of claims 15, 25, 26, 45, 55, 56, and 73-78 as obvious over Castro is reversed.

5) The rejection of 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48, 49, 51-53, and 71-78 as obvious over Ding and You is reversed.

6) The rejection of claims 54-58 and 60 as obvious over Ding and You is affirmed.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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